

# **EXHIBIT 52**

PLAINTIFFS' EXHIBITS 000083

**ACTAVIS TOTOWA LLC.**

**IN - PROCESS DISPOSITION FORM**

PRODUCT: Degoxin Tablets, USP 0.25 mg

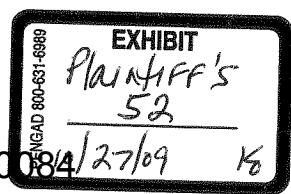
STAGE : FINAL BLEND \_\_\_\_\_ BATCH. NO: 70670 A

**DISPOSITION: RELEASE**

RETEST DATE: 09/09/07

COMMENTS: DRUM # 1 To 5

DISPOSITIONED BY: M. Q.R. DATE: 08/22/07



PLAINTIFFS' EXHIBITS 000-084 27/09 K

Actavis Totowa LLC

## IN-PROCESS TESTING (BLEND SAMPLE) TEST REPORT

Product: Digoxin Tablets, USP 0.25 mg			
MOI #: 145	Revision #: 08	Product ID #: 146	Page 1 of 1
Prepared By: <i>Lamman Murphy</i>	Date: 03/19/07	Approved By: <i>Malott 03/27/07</i>	Effective Date: 07/12/07

Batch #	70670 A	Theoretical tablet weight:	120.0 mg
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TEST (Source)	SPECIFICATION	RESULT	REFERENCE Volume/Page/ Chemist/Date
Description (In-house):	White to off-white colored slug or free flowing powder	white to off-white free flowing powder	0102/22 AKP 08/16/07
Blend Uniformity (in-house):			0102/22 AKP 08/16/07
Center - Top		92.4%	
Center - Middle		95.8%	
Center - Bottom		97.0%	
Left Slope		95.6%	
Right Slope		95.1%	
Left - Middle		94.5%	
Left - Top		95.2%	
Right - Middle		94.9%	
Right - Top		97.8%	
Front - Middle		94.2%	
Average:	90.0% - 110.0%	95.2%	
RSD:	NMT 5.0%	1.5%	

<input checked="" type="checkbox"/> COMPLIES	<input type="checkbox"/> DOES NOT COMPLY
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Reviewed By: JCS  
Date: 08/21/07

DATA APPROVAL

By: <u>J. DeAngelis</u>	Date: <u>08/22/07</u>
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TOTOWA LLC

## Laboratory Analysis Request Form

Name:	Digoxin Tablets USP 0.25mg		
Identification #:	Pond ID # 146		
Batch/PO/Lot #:	Batch # 706701		
Sample Type: (Specify interval, fill and conditions for stability samples)	Final Blend		
Sample Size/Amount:	As per attached submission form		
Testing Required:	<input checked="" type="checkbox"/> Per Product Specifications <i>in process</i>		
	<input type="checkbox"/> Other (Specify):		
Additional Information/Comments:	N/A		
Requested By:	DR	Date:	08/11/07
Dept:	QA		

For QC Use Only			
Sample ID #:	0668		
Issued By:	CDP	Date:	08/11/07
Comments:	30 samples, of final blends, consist of 3 sets.		

ACTAVIS TOTOWA LLC

QA SAMPLE SUBMISSION FORMItem # N / A Item Name: N / A

IN - PROCESS / FINISHED PRODUCT:

MPR # 14602 - 10 Product : Digoxin Tablets, USP 0.25mgStage: Final Blend ( Set: 1 ) Batch # 70670A

SAMPLE DESCRIPTION: Blender # 36

	TARE Wt.	GROSS Wt.	Net Wt:
1 Center - Top	14978	15297	319 mg
2 Center - Middle	15058	15388	330 mg
3 Center - Bottom	14972	15307	335 mg
4 Left - Slope	15038	15355	317 mg
5 Right - Slope	15053	15350	297 mg
6 Left - Middle	14996	15285	289 mg
7 Left - Top	14962	15310	348 mg
8 Right - Middle	15070	15360	330 mg
9 Right - Top	15017	15302	285 mg
10 Front - Middle	14989	15275	286 mg

Theo. Wt: 120.0 mg

TESTING REQUIRED :

As per in process specification

Submitted BY : DR Date : 08/16/07

Submitted on 8/16/07

QA119.0

PLAINTIFFS' EXHIBITS 000087

ACTAVIS TOTOWA LLC

QA SAMPLE SUBMISSION FORM

Item #	N / A	Item Name:	N / A
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IN - PROCESS / FINISHED PRODUCT:

MPR # 14602 - 10 Product : Digoxin Tablets, USP 0.25mgStage: Final Blend ( Set: 2 ) Batch # 70670A

SAMPLE DESCRIPTION: Blender # 36

	TARE Wt.	GROSS Wt.	Net Wt:	
1 Center - Top	<u>14994</u>	<u>15290</u>	<u>296</u>	mg
2 Center - Middle	<u>15069</u>	<u>15380</u>	<u>311</u>	mg
3 Center - Bottom	<u>15173</u>	<u>15473</u>	<u>300</u>	mg
4 Left - Slope	<u>15647</u>	<u>15360</u>	<u>313</u>	mg
5 Right - Slope	<u>15030</u>	<u>15340</u>	<u>310</u>	mg
6 Left - Middle	<u>15010</u>	<u>15291</u>	<u>281</u>	mg
7 Left - Top	<u>15054</u>	<u>15333</u>	<u>279</u>	mg
8 Right - Middle	<u>14994</u>	<u>15308</u>	<u>314</u>	mg
9 Right - Top	<u>15022</u>	<u>15314</u>	<u>292</u>	mg
10 Front - Middle	<u>15024</u>	<u>15324</u>	<u>300</u>	mg

Sample not tested

Theo. Wt: 120.0 mg

TCS  
08/21/07

TESTING REQUIRED :

As per in process specification

Submitted BY : JR Date : 08/10/07

Submitted on 8/11/07

QA119.0

PLAINTIFFS' EXHIBITS 000088

ACTAVIS TOTOWA LLC

QA SAMPLE SUBMISSION FORMItem # N / A Item Name: N / A

## IN - PROCESS / FINISHED PRODUCT:

MPR # 14602 - 10 Product : Digoxin Tablets, USP 0.25mgStage: Final Blend ( Set: 3 ) Batch # 70670A

## SAMPLE DESCRIPTION: Blender # 36

	<b>TARE Wt.</b>	<b>GROSS Wt.</b>	<b>Net Wt:</b>
1 Center - Top	<u>15144</u>	<u>15450</u>	<u>306</u> mg
2 Center - Middle	<u>15026</u>	<u>15323</u>	<u>297</u> mg
3 Center - Bottom	<u>15103</u>	<u>15405</u>	<u>302</u> mg
4 Left - Slope	<u>14968</u>	<u>15265</u>	<u>297</u> mg
5 Right - Slope	<u>15083</u>	<u>15392</u>	<u>309</u> mg
6 Left - Middle	<u>15028</u>	<u>15333</u>	<u>305</u> mg
7 Left - Top	<u>15030</u>	<u>15329</u>	<u>299</u> mg
8 Right - Middle	<u>14997</u>	<u>15328</u>	<u>321</u> mg
9 Right - Top	<u>15087</u>	<u>15380</u>	<u>293</u> mg
10 Front - Middle	<u>14943</u>	<u>15280</u>	<u>337</u> mg

Sample not testedJCS

Theo. Wt: 120.0 mg

06/21/07

## TESTING REQUIRED :

As per in process specification

Submitted BY : DR Date : 08/10/07

Submitted on 8/11/07 QA119.0

PLAINTIFFS' EXHIBITS 000089

Actavis Totowa LLC

Department Operating Instruction

## TITLE: Evaluation of Laboratory Error

DOI: QC-106

Revision: 04

ATTACHMENT

## LABORATORY ERROR EVALUATION REPORT

Product: Digoxin Tablets, 0.25 mg, USP		Batch/Lot: 70670A
Laboratory Error Number: LEN 07- 065		Date Initiated: 08/17/07
Test: Blend Uniformity		MOI/Method: # 145 Rev: # 08
Date Incident Occurred: 08/17/07		Sample: Final Blend (i.e., raw material, in-process, finished product, stability with time/conditions, etc.)
Instrument ID: HPLC# 14		
Analyst: AKP	Date: 08/17/07	Book: 0102 Page: 22

## Background:

Analyst was performing blend uniformity test for above batch using MOI# 145, REV# 08. Analyst selected wrong TotalChrom method and sequence for HPLC testing. MOI# 145 having two different methods.

For Digoxin Tablets 0.125 mg method ID# 145 and Digoxin Tablets 0.25 mg method ID# 146. Testing was performed according to method ID# 146 and found the results within product specification.

Analyst misinterpreted MOI to select the TotalChrom template for method and sequence, instead of ID# 146 template analyst selected ID# 145.

## Action:

Analyst was instructed to calculate the results using Quattro-pro program and compare the results obtained from TotalChrom software.

## Conclusion:

The results using Quattro-pro program and TotalChrom software were the same and are within product Specifications.

Analyst: AKP Date: 08/17/07 Supervisor: ofer Date: 08/17/07

Approval:  Evaluation is completed.

QC Director: S. Rosenblatt Date: 08/22/07